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Report Highlights:
This report is meant to describe the current status of biotech products in Romania. Commercial planting and field testing are both allowed. Draft law to impose a moratorium on biotech crops is under debate in the Romanian Parliament.

Section I. Plant Biotechnology Trade and Production

Romanian farmers have accumulated large experience in planting biotech soybeans prior to membership to the European Union (January 1-st 2007), which ended their access to this technology. In 2001, Romanian farmers planted 15,000 hectares with biotech soybeans and the figure steadily climbed as farmers experienced the advantages of this new technology, especially in response to Romania's huge weed reserve. The area under soybeans in 2006 reached 190,000 HA, generating a production of about 380,000 MT. Almost 70% of this area (130,000 HA) was planted with biotech soybeans.

Since the prohibition of biotech soybean planting, acreage covered with soybeans declined drastically, reaching in 2010 only one third (64,000 HA) of the area planted in 2006, as farmers' interest is lower because of high production costs. A similar soybean area is expected to be harvested in 2011.

Currently the only genetically modified (GM) crop under commercial cultivation in Romania is corn, MON 810, insect resistant. According to recent data, farmers planted in 2011 an area of nearly 600 HA with biotech corn, for both consumption and production of planting seeds, which is 28 percent drop compared to the previous year.

Since the domestic soybean production is insufficient, the feeding demand for livestock and poultry industry is covered from imports of soybeans and soy meal, which reached in 2010 about 450,842 MT ($183 million), of which soybeans 435,000 MT ($175 million). Large biotech products producing countries are the major suppliers: Brazil (255,000 MT), Argentina (98,797 MT) and United States (20,613 MT). Other feed ingredients, such as Distilled Dry Grains Soluble (DDGS) and Corn Gluten Feed (CGF) are accepted by the domestic industry in limited volumes (Romania imported 1,170 MT of CGF in 2010).

Field testing is allowed for biotechnology crops in Romania. Appendix 1 provides the list of companies authorized in 2010 to conduct field trials in specific locations and for certain biotech events. The authorizations are valid in general for up to 5 years. Import permits for biotech products subject to those field trials are needed only for the first shipment of each product, but an import approval has to be issued each year by the Ministry of Agriculture for the imported hybrids.

In 2011, seeds companies submitted several notifications for field testing for corn, sugar beet and plum trees (Appendix 2). However, in the absence of a functional Biosafety Commission, these notifications have not been yet assessed, thus the authorizations are pending until the Biosafety Commission becomes operational.

Section II. Plant Biotechnology Policy

Romania transposed the Directive 2001/18 regarding the deliberate release into the environment of genetically modified organisms through Emergency Ordinance 43/2007 (Law 247/2009) and Directive 90/219 referring to contained use of genetically-modified micro-organisms through Emergency Ordinance 44/2007.

In addition to these, other major pieces of legislation were passed prior to accession in accordance with the country's EU accession commitments, especially related to traceability and labeling of food products derived from GMO, which are Government Decision 173/2006 (transposing Regulation (EC) No 1830/2003) and Government Decision 256/2006 (transposing Regulation (EC) No. 1829/2003).

Order 55 regarding the national registry for information recordings on genetic modifications issued in 2007 by the Ministry of Environment and Forests (MEF) is still valid. Order 471/2006 issued by the Ministry of Agriculture and Rural Development (MARD) amended Order no. 237/2006 concerning authorization of GM plants cultivators, while Government Decision 497/2007 transposed the EC Regulation 1946/2003 on transboundary movements of genetically modified organisms.

The Regulatory Bodies

According to Emergency Ordinance 43/2007 (Directive 2001/18) regarding the deliberate release of GMOs in the environment and on the market, the competent authorities in implementing and enforcing all activities related to the use of GMOs, and all activities concerning the deliberate release of GMOs are:

1. the central public authority for environment protection - Ministry of Environment and Forestry (MEF), which coordinates and ensures the application of precautionary principle to avoid potential adverse effects of GMOs on human health and environment as a result of obtaining, using and commercializing these organisms

1. the Competent Authority (CA) which is in this case, the National Agency for Environment Protection (NAEP), whose main responsibilities are:
    - receive, administer and assess the technical content of the notifications
    - consult with all responsible bodies including the Biosafety Commission
    - issue, revise, suspend or cancel authorizations/approvals
    - ensure there is a functional national laboratory for GMOs detection and determination
    - establish and administer the electronic registry for notifications, authorizations, approvals and their status

- establish and administer the Registry for data on GMOs import, export and transit.

1. National Guard for Environment (NGE) is the control authority ensuring the right enforcement of this Directive provisions

1. the Ministry of Agriculture and Rural Development (MARD), the Sanitary-Veterinary and Food Safety National Authority (ANSVSA), and the Ministry of Public Health (MPH) also have roles in implementing this Directive.

Biosafety Commission

The Biosafety Commission (BSC) existed in Romania since 2002 as a scientific body with consultative role in assisting the authorities in the decision-making process regarding the issuance of authorizations/notifications. In 2008, Ministry of Environment issued Order 98, setting the main responsibilities of the Biosafety Commission, including the list of members. BSC has the following major responsibilities:

- scientifically assess the notifications in respect to risks on human health and environment;
- issue a scientific approval; the notices and the minutes of their meetings are not confidential and they have to be submitted to the CA, in both Romanian and English
- work with the competent authority and other parties for drafting the necessary measures in case of major risks and in case of safeguard clause
- work with the central public authority for environment protection for designing policies and strategies concerning biosafety and drafting new legislation.

Per the provisions of Law 247/2009, the following entities may advance nominations for the Biosafety Commission members to the Ministry of Environment:

- Romanian Academy for 3 members and one alternate
- Academy for Agricultural Science for 3 members and one alternate
- Academy of Medical Science for 3 members and one alternate
- Universities and research institutes covering specific subject areas for 3 members and one alternate

Therefore the Ministry of Environment has to approve the new BSC members through a Ministerial Order based on the nominations received. Currently the Biosafety Commission is not functional, and the approval of a new Commission is pending.

Co-existence between biotech and non-biotech crops

The provisions of Emergency Ordinance 195/2005 concerning environment protection, approved through Law 265/2006 and amended in 2008 by Emergency Ordinance 164/2008 are still valid.

According to Order 237/2006 issued by the Min. of Agriculture, biotech farmers have to avoid cross-contamination by setting a minimum isolation distance between the biotech and conventional fields, according to the general regulations on seeds certification. Farmers should also establish a "buffer zone" and carefully plan the sowing season. In case of biotech corn, per the provisions of Order 149/2010 concerning seeds commercialization issued by the Ministry of Agriculture, the minimum isolation distance is 200 m. During harvesting, transportation and storage process farmers have to avoid commingling GM seed with organic or conventional seeds through separate storage, through cleaning of machinery for sowing and conditioning, cleaning transportation means, according to specific legislation on certified seeds. It is mandatory that biotech farmers notify in writing both land owners and land users with plots near-by about their intention to cultivate biotech plants.

In October 2009, the competent authority for environment protection issued Order 1205 allowing the publication of detailed information about the farmers planting biotech crops. The catalog is named "National Register regarding the locations used for deliberate release of GMOs into the environment", with two sections, one for biotech crops intended for testing and one for biotech crops intended for commercial use.

The register is publicly available on the website of Ministry of Agriculture. The register concerning the commercial biotech fields provides the following data about the famers and the biotech seeds: 1. Year 2. Genetically modified organism*: a) species b) transformation event c) unique identification code d) other specific data* 3. The owner of authorization for commercial cultivation at European Community level 4. Information about the economic operator: name, address (premises for commercial company, home address for individuals), fiscal accounting number / personal code 5. Locations (locality/county) 6. Planted area (HA) 7. Information regarding the distances to conventional/organic crops 8. Information concerning the authorization for commercial planting (validity term, provisions) 9. Monitoring report issued by the owner of the authorization or other bodies in charge with monitoring. Similar information is published in the register concerning the field trials.

Labeling

National legislation concerning GM labeling was fully brought in line with the EU requirements (Regulation (EC) No 1830/2003) through GOR Decision No. 173/2006. Romania adopted measures on thresholds for labeling, set at 0.9% for an adventitious presence of an authorized GM in food or feed. Operators must demonstrate that the presence of GM material was adventitious or technically unavoidable.

Animal feed, if produced from GM crops, is required to be labeled, according to GOR Decision 256/2006 in place starting with January 1, 2007. Nevertheless, meat, milk or eggs obtained from animals fed with GM feed or treated with GM medicinal products do not require GM labeling.

Traceability

The GOR Decision 173/2006 represents the regulatory framework to ensure full traceability of biotech products in Romania. According to this decision, all operators involved in this business along the commercial chain must transmit and retain information about products that contain or are produced from GMOs at each stage of placing them on the market. Accurate information concerning the presence of GMOs must be retained for five years. The regulation covers all products, including food and feed, containing or derived from authorized GMOs.

Traceability elements are also provided in the Order 237 issued by MARD in 2006, amended by Order 471/2006. According to this order, biotech farmers have to seek for authorization from the county office of MARD, for each plot intended to be cultivated with GM crops. GM seeds are forbidden for cultivation in the near "vicinity" of certified organic areas or areas under the conversion process. The order does not define the term "vicinity" though. The order also sets a minimum size of 2 HA for a field to be planted with biotech crops (except the field trials).

Biotech farmers can only use certified seeds. Upon sowing completion, within 7 working days, the farmers must report to the county office of MADR facts on planted area, seeds source and the varieties used. A copy of their declaration should be retained for 5 years. Similarly, upon harvesting completion, within 7 working days, the farmers must submit to the county office of MADR data on production obtained and its purpose. When delivering the GM products further on the commercial chain, farmers have to clearly specify on the accompanying documents and labels the GM product unique identifier and the fact that the products are genetically modified.

According to Order 471/2006, farmers must submit to the county offices of MADR during the first 5 days of every month the information concerning the buyers of the GM crop. These offices will provide before the date 15 of each month, information on stocks, volumes delivered by each farmer, buyer information, and production destination to the county offices of NGE. Order 471/2006 also provides a list of inspectors from the county offices of MADR officially certified to perform control activity on the observance of legislation concerning GMOs.

Authorization Procedure

Emergency Ordinance 43/2007 lays down the main phases of approval process for GMO deliberate release into the environment for placing on the market or other purposes.

In case of deliberate release into environment for other purposes than marketing, the user shall submit a notification to the

CA, prior to deliberate release into the environment of any GMO or combination of GMOs. The notification content is in details described by this Ordinance.

The authorization procedure starts when the notification is accepted. Within 10 days from that moment, the CA will send a copy of notification to each of the authorities with roles in the approval process (MARD, ANSVSA, MPH, NGE) and to the Biosafety Commission for an assessment. The European Commission is also entitled to receive a copy of notification. The Biosafety Commission is expected to provide the CA and the other authorities involved in this process, a scientifically based assessment within 60 days.

Upon receipt of the notification, and no later than 5 days, the CA allows public to comment on the notification for a period of 30 days. Within the next 10 days after the 30-day period is complete, the CA will inform the MEF and the other responsible authorities, including the Biosafety Commission, about the public opinion.

Within 90 days from the start of authorization process, the CA will prepare an assessment report based on the scientific statement of the Biosafety Commission, the input of the other authorities and the public comments. The assessment report can make a favorable decision, in which case an authorization is issued, or an unfavorable decision, in which case, no authorization is granted.

Every year, no later than December 15, the user will submit to the regulators a report with the findings of the deliberate release of GMO into the environment during that year.

Monitoring

Orders 838/2005 and 606/2005 issued by the Ministry of Environment describing the Monitoring Plan and the format for presenting the results of the monitoring activity remain in place in case of deliberate release for other purpose than market placing. The monitoring activity will follow clear procedures and will be conducted according to a plan submitted by the notifier and can be carried out for restricted use and/or after obtaining the approval for GMO release into the environment or placing it on the market. If new information appears as a result of the monitoring, this should, by default, be incorporated into future risk assessment studies.

Order 838/2005 issued by the Ministry of Environment describes the Monitoring Plan, which is part of the notification dossier and includes three sections: Monitoring strategy, Monitoring Methodology and Assessment, reporting, reassessment.

The notifier should submit the Monitoring reports to Ministry of Environment, which will forward them to the EU Commission and other competent authorities. The notifier is responsible for ensuring transparency in the monitoring plan results through workshops, dissemination of materials, webpage publications, and scientific and commercial magazines. Order 606/2005, fully transposing Commission Decision no. 2003/701/EC, approves the format (template) for presenting the results of the monitoring activity.

Enforcement

Various government agencies play different roles in enforcing the current legislation related to the national biosafety system. The following authorities bear responsibilities for inspection and control activities:

1. The Ministry of Environment and Forests (MEF) – through the National Guard for Environmental (NGE), as NGE is in charge with enforcing the whole package of environmental protection legislation (via inspection and control).

2. The Ministry of Agriculture and Rural Development (MARD), in which several departments with official inspection and control capacity have responsibilities related to GMOs, such as the *Division for Agricultural Policies Implementation* - with roles in authorizing local GMO plantings and in gathering information about biotech farmers per provisions of Order 237/2006 and *the National Inspection for Seed Quality* and *the State Institute for Variety Trials and Registration* (Romanian acronym ISTIS) that investigates from the technical point of view the varieties for which requests have been made to be registered in the Variety Register and the Official Variety Catalogue.

3. The Veterinary and Food Safety National Authority (ANSVSA). With respect to GMOs, ANSVSA is involved in (i)

endorsing approvals for GM products from the perspective of assessing potential risks to human and animal health; (ii) exerting control regarding the enforcement of food and feed traceability requirements.

4. The National Authority for Consumer Protection (NACP), which checks on the enforcement of food product labeling requirements in order to ensure that correct, complete and accurate information is provided to consumers, including products containing or consisting of GMOs.

Several laboratories are operational and able to perform tests for GMOs detection. The National Reference Laboratory for GMO testing is the Molecular Biology and GMO Unit, part of the Institute for Diagnosis and Animal Health (IDAH) for food and feed. There are several other laboratories accredited or on the course of accreditation for performing detection tests either for planting seeds (for the purpose of seeds certification) or for co-existence rules.

Intellectual Property Rights

This aspect is regulated in Romania via a number of laws and Government Decisions: Law 285/2004 on copyright and connected rights, Government Decision 1424/2003 for approving the National Strategy in Intellectual Property Rights with amendments in 2005, Government Decision 573/1998 concerning the Organization of the State Office for Inventions and Trademarks (OSIM).

The State Office for Inventions and Trademarks was until July 2011 the authority where plant companies could have applied for protecting their plant varieties. Information regarding the steps to be undertaken by any party interested to apply for a patent is still available on the OSIM website (www.osim.ro), although starting with July 2011, ISTIS is the body responsible for protecting the crop varieties (www.istis.ro).

In respect to the biotech seeds available for cultivation (MON 810 corn), unlike before 2007 when royalties were not collected for biotech soybean technology, farmers purchasing these biotech seeds are presently paying a "technology fee" to the supplier.

Proposal for a moratorium on biotech crops cultivation

In May 2010, the National Liberal Party introduced in the Parliament a draft law intended to prohibit biotech crops planting in Romania for 5 years. About 78 members of the Romanian Parliament signed on the draft, out of total number of 471. The first chamber to discuss the proposal was the Senate, and Romanian Senate rejected the initiative in November 2010. Presently the draft is under debate within the Chamber of Deputies. The draft includes two parts: (1) prohibition of biotech crops cultivation; (2) labeling of food products containing GM ingredients or originating from animals fed with GM feed.

Although in another form, the labeling issue has been subject to debate twice so far in the Parliament and it was rejected both times, in 2008 and 2010. According to the previous proposal, the label would have contained the warning "Attention, this product contains genetically modified organisms" written in black color inside a yellow spot. This warning should cover 30% of the total surface of the product. The Romanian Government did not support the proposal arguing that EU biotech legislation is already in place in Romania and imposing national labeling rules would be discriminative and would contravene to EU Treaty provisions.

This is the first time when an initiative prohibiting biotech crops cultivation reaches the Parliament level. Ministry of Environment had a similar initiative in 2008, but the favorable resolution issued that time by the Biosafety Commission for biotech corn prevailed.

The perspective of placing a moratorium on biotech crops prompted a strong reaction from agricultural producers united under LAPAR organization. In an open letter sent to the Romanian President, LAPAR criticized the proposal to prohibit the biotech crops cultivation while allowing the consumption at EU level. In an attempt to make the Romanian authorities be more responsible, LAPAR asked the President to support the ban on biotech foods derived from biotech crops at EU level, including imports, if they assess them as harmful for human and animal health. LAPAR warned further that the hostile attitude to agricultural biotechnology will lead to a further expansion of idle fields, already reaching a considerable percentage in the total arable land.

Section III. Plant Biotechnology Marketing Issues

Given the weight of Romania's votes in the Council of the European Union, Romania's stance on Biotech products became an important topic for debate in circles of scientists, farmers and industry representatives as well as media players.

Over time, the Minister of Agriculture, Valeriu Tabara, expressed in numerous occasions his views regarding the need to modernize agriculture and advocated for farmers' access to better technologies in agriculture. Green organizations criticized the Minister for being a supporter of agricultural biotechnology, thus AgMinister stated that the biotechnology decisions for which Ministry of Agriculture is responsible are science-based and in line with the Scientific Opinion issued by the European Food Safety Authority. Moreover, country position is drafted after consultation with other involved authorities, such as Food Safety Authority, Ministry of Environment and Forests, Consumer Protection Authority and European Affairs Department.

As a reaction to this criticism, over 50 farmers' associations from both crop and animal sectors publicly asked the Prime-Minister and the President to support the AgMinister in regard to his efforts for advancing biotech crops. In their view, biotech crops represent a mean to guarantee incomes and protect environment, bringing to economy total savings of 1 billion EURO/year along the whole commercial chain (farmer to consumer). With another occasion, farmers reiterated their wish to cultivate biotech soybeans, which may lead to higher productivity and pollution diminution because of the lower chemicals usage.

Under the pressure of ecological group, some mayors declared the territory under their jurisdiction "GMO free-areas". Most of these areas are located in regions less favorable for agriculture or represent municipalities with no agriculture on large-scale. Declarations referring to "GMO-free areas" and the statements that trade and cultivation are prohibited inside those areas have only an intimidating purpose since such initiatives should be notified to the EU Commission (if fully in accordance with the EU legislation).

In terms of education, various stakeholders organizing conferences on agriculture often introduce Agriculture Biotechnology as a major topic. Most of the debate lies in the fact that Romania is not allowed to plant biotech soybeans (as it did prior to EU accession), while the livestock industry becomes a large user of imported biotech soybeans. The number of media channels organizing events concerning the use of biotechnology has been steadily growing.

In addition to conferences, a growing number of articles are written on this topic. Specialized agricultural magazines are more prone in publishing facts about biotech crops and imported volumes, while among regular dailies, only several convey to their readers a complete set on information about modern technologies in agriculture. It is obvious there is a need for further education in this field, and that will be meaningful especially in the current context of the EU allowing Member States to decide on biotech crops cultivation on their own territory, which is expected to intensify the public debate on this topic.

Section IV. Plant Biotechnology Capacity Building and Outreach

In March 2009, Jack Bobo, the Dept. of State advisor on Biotech visited Romania to meet with Romanian government officials concerning the benefits of agricultural biotechnology. Mr. Bobo participated in a round-table with officials from several agencies to discuss biotech safety and was interviewed by few journalists.

In January 2011, United Soybean Board (USBB) conducted a very successful one-day trip in Romania, as a result of the very dense schedule and diversity of people the delegates met. USB discussed with their interlocutors about the impact of the EU's biotech policy on European agriculture and soybeans imports, as well as about the biotech crops in the pipeline that will bring benefits to consumers. Romanian livestock producers were concerned about possible interruptions in soybean trade, while farmers were looking forward to re-gaining the access to biotech soybeans for cultivation. The visit was widely covered in specialized agricultural magazines.

In April 2011, the Romanian Academy jointly with the Academy for Agricultural Science and Forestry published their point of view concerning the biotech products, emphasizing that these are products are safe for consumption. The document

includes a list of projects conducted by various entities in Romania, such as Agricultural Universities, World Bank, Romanian Academy.

AgroBiotechRom Association has been funded as a voice of the producers and users of agricultural biotechnology in Romania, having as member biotech seeds companies, farmers and representatives of the academic environment. The role of the association is to increase awareness among consumers related to benefits of biotechnology in health, agriculture and industry sectors and to support the expansion of biotechnology utilization in Romania, given its potential for better productivity and less use of resources.

V. RELEVANT REFERENCES

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APPENDIX 1

Table of Approved Biotechnology Products in Romania for testing (2010)

Crop	Trait Category	Applicant(s)	Transformation Event	Trait Description	Approved for
Corn/ Zea mays L.	Staked genes (Herbicide Tolerance and Insect resistant)	Monsanto	MON-89034-3 x NK 603	Glyphosate tolerant and resistance to Lepidoptere insects	Field Trials
Corn/ Zea mays L.	Staked genes (Herbicide Tolerance and Insect resistant)	Monsanto	MON-89034-3 x MON-88017-3	Glyphosate tolerant and resistance to Lepidoptere and Coleoptere insects	Field Trials
Corn/ Zea mays L.	Staked genes (Herbicide Tolerance and Insect Resistance)	Pioneer	1507 x NK 603	Glyphosate Ammonium and Glufosinate - tolerant and Lepidopteran insects resistant	Field trials
Corn/ Zea mays L.	Staked genes (Herbicide Tolerance and Insect Resistance)	Pioneer	NK 603 x MON810	Glyphosate tolerant and Lepidopteran insects resistant	Field trials
Corn/ Zea mays L.	Herbicide Tolerance	Pioneer	NK 603	Glyphosate tolerant	Field Trials
Corn/ Zea mays L.	Herbicide Tolerance	Monsanto	NK 603	Glyphosate tolerant	Field Trials
Corn/ Zea mays L.	Herbicide Tolerance	Limagrain Central Europe SE France	VCO-01981-5	Glyphosate tolerant	Field trials

APPENDIX 2

Table of Biotechnology Products notified (authorizations pending) for field testing in Romania (2011)

Crop	Trait Category	Applicant(s)	Transformation Event	Trait Description	Approved for
Corn/ Zea mays	Herbicide Tolerance	Monsanto	NK 603	Glyphosate tolerant	Field Trials
Sugar Beet/Beta vulgaris	Herbicide Tolerance	Monsanto	H7-1	Glyphosate tolerant	Field Trials
Plum tree/Prunus Prunus Domestica	Virus resistant	Research and Development Station Bistrita	PPV	Plum pox virus resistant	Field Trials
Corn/ Zea mays L.	Insect resistant	Pioneer Hi-Bred Seeds Agro	DAS-59122-7	Resistance to Coleoptere insects	Field Trials
Corn/ Zea mays L.	Staked genes (Herbicide Tolerance and Insect resistant)	Pioneer Hi-Bred Seeds Agro	DAS-59122-7 x 7-DAS01507-1x MON 603	Glyphosate tolerant and resistance to Coleoptere insects	Field Trials